Please replace the paragraph beginning on page 29, line 12 with the following paragraph:

--FIGS. 28D, 28E and 28F depict HPLC chromatograms of 35% plasma/65% PAS III containing non-illuminated S-59 (Figure 28D), illuminated S-59 (Figure 28E), and illuminated S-59 treated with Amberlite XAD-4™ (Figure 28F), and adsorption was contained in a 30 μm nylon mesh enclosure/pouch, and the contact time was three hours.--

Please replace the paragraph beginning on page 30, line 26 with the following paragraph:

--FIGS. 38A and 38B depict a production flow chart of many of the steps used in manufacturing a batch removal device.--

Please replace the paragraph beginning on page 31, line 4 with the following paragraph:

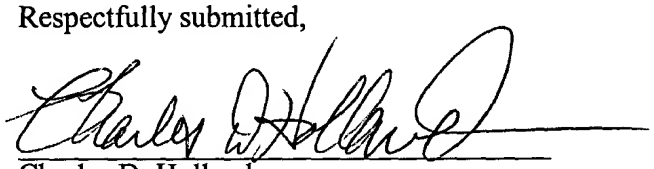
--FIGS. 41A, 41B and 41C depict chromatograms of PC, containing 150 μM S-59 (15.2 mg/300 mL), showing levels of S-59 and free photoproducts before illumination with UVA (Figure 41A), following illumination with UVA (Figure 41B), and following illumination with UVA and an 8-hour incubation with a RD containing Dowex® XUS-43493 (Figure 41C) and housed within a PL 2410 Plastic container (Baxter).--

REMARKS

Attached hereto is a marked-up version of the changes made to the specification by the current amendment. The attached page is captioned "**Version with markings to show changes made**".

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 282172000810. However, the Assistant Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

Dated: June 1, 2001 By: 

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"Version with Markings to Show Changes Made"

In the specification:

Paragraph beginning on page 31, line 18:

[Schematic A]Figure 45 diagrammatically depicts the distribution of S-59 in platelets suspended in 35% plasma/65% PAS III following illumination with UVA.

Paragraph beginning on page 31, line 20:

[Schematic B]Figure 46 is a graph showing the effect of the final S-59 concentration on the amount of adsorbent required (initial concentration, C_o = 30 μM and a volume, V = 300 ML). The "K-values" for each curve are listed in the legend.

Paragraph beginning on page 31, line 23:

[Schematic C]Figure 47 depicts two possible configurations for a batch RD. Configuration A illustrates a two-bag design whereas configuration B illustrates a single-bag design.

Paragraph beginning on page 31, line 25:

[Schematic D]Figure 48 diagrammatically depicts the S-59 reduction process. Following illumination of the PC containing S-59, the PC is transferred to a container housing the RD, incubated with agitation to allow a time-dependent reduction in the amount of residual S-59 and unbound photoproducts, and then transferred to a storage container.

Paragraph beginning on page 32, line 1:

[Schematic E]Figure 49 depicts a flow diagram summarizing the operation of a hypothetical apheresis system in which one embodiment of the RD of the present invention may be employed.

Paragraph beginning on page 32, line 4:

[Schematic F]Figure 50 depicts an alternative embodiment of the present invention in which PAS III is added during the platelet collection procedure.

Paragraph beginning on page 32, line 6:

[Schematic G]Figure 51 depicts an alternative embodiment of the present invention in which PAS III combines with S-59 and then is added during the platelet collection procedure.

Paragraph beginning on page 74, line 1:

The final equilibrium solution concentration, C_f, is an important parameter since it determines both the resin capacity, q, and the total amount of S-59 which must be removed. Combining Equation 1 and Equation 2 yields the following relationship:

$$M = (V/K)[(C_o/C_f)-1] \qquad \text{(Equation 3)}$$

Of note, for low values of C_f, the required mass of resin, M, is inversely proportional to C_f. The asymptotic behavior of adsorbent mass with respect to C_f is set forth in [Schematic B]Figure 46. Equation 3 was used to derive the curves presented in Schematic B, and calculations were based on an initial concentration, C_o of 30 μM and a volume, V, of 300 mL.

Paragraph beginning on page 79, line 3:

[Schematic C]Figure 47 depicts two possible configurations for a batch RD. In configuration A (i.e., a two-bag design), platelets are transferred to a second bag following

illumination, the second bag containing the adsorbent in a mesh enclosure/pouch. The platelets could be transferred back to the original bag if a limited contact time is desirable. In configuration B (i.e,., a single-bag design), the external partition is broken away following illumination, thereby allowing the platelets to freely mix with the adsorbent bag/pouch. Of course, other configurations are possible for a batch RD.

Paragraph beginning on page 84, line 24:

In an alternative embodiment, UVA illumination and RD treatment occur in a single blood product bag. In this embodiment, a removable, external partition separates the blood product bag into two compartments (see [Schematic C]Figure 47, configuration B). Referring to [Schematic C]Figure 47, configuration B, the blood product is illuminated in the lower compartment. Following illumination, the partition is removed and the illuminated blood product contacts the RD that is fixed within the upper compartment. After incubation, the blood product bag may be hung up and the partition replaced, thereby isolating the blood product from the RD. Alternatively, the bag may be welded (e.g., heat sealed or impulse welded) to isolate the blood product from the RD. The entire blood product bag (i.e., the bag including the illuminated and RD-treated blood product and the RD itself) may then be stored pending transfusion.

Paragraph beginning on page 106, line 4:

The present invention contemplates the use of a psoralen decontamination and a batch RD with an apheresis system. Though several procedures are summarized below, the present invention is not limited to any particular means of incorporating the batch RD into the operation of an apheresis system. In order to assist in understanding the discussion that follows, a flow diagram summarizing the operation of a hypothetical apheresis system is depicted in [Schematic E]Figure 49. It should be emphasized that the diagram in [Schematic E]Figure 49 is meant to depict the possible flow of fluids through an illustrative design for an apheresis system and is not

intended to depict any actual apheresis procedure. Those skilled in the art will appreciate that apheresis procedures might include different fluid flow pathways and different components or arrangement of components than those shown in [Schematic E]Figure49.

Paragraph beginning on page 106, line 15:

Referring to [Schematic E]Figure 49, whole blood is withdrawn from a donor 500 and into an inlet line 502. An anticoagulant pump 506 pumps an anticoagulant from an anticoagulant container 508 through an anticoagulant line 509 that exits into the inlet line 502. The anticoagulant-containing whole blood is then pumped by an inlet pump 516 into a centrifuge 520. it should be noted that some apheresis machines utilize a single pump instead of separate anticoagulant and inlet pumps. The centrifuge 520 separates the blood into its various components, such as white blood cells, red blood cells, platelets, and plasma.

Paragraph beginning on page 108, line 17:

For example, in one alternative embodiment, the platelets ultimately collected in the platelet collection container already contain the appropriate quantity of platelets and amounts of PAS and plasma. [Schematic F]Figure 50 is a modified version of [Schematic E]Figure 49 depicting the platelet collection procedure in this alternative embodiment. In addition to having the platelet storage container 538 and the autologous plasma container 528, this embodiment contains a bag 539 containing a pre-determined amount of PAS III (or other suitable synthetic media). After or simultaneous with platelet collection, an appropriate amount of collected autologous plasma (e.g., 105 mL) and an appropriate amount of PAS III (e.g., 180 mL) are automatically added to the platelets; this may be performed by adding the PAS III and the plasma through tubing 562 that bypasses the centrifuge 520 and enters the platelet storage container 538. Thus, because the addition of PAS III is integrated into the platelet collection procedure, this

embodiment eliminates the sterile docking procedure (see Experimental section) otherwise required to add the PAS III solution.

Paragraph beginning on page 110, line 7:

Another embodiment contemplated by the present invention involves the use of a container 560 containing S-59 positioned between a PAS III-containing bag 539 and the platelet collection container 538. (See [Schematic G]Figure 51) As the PAS III is being added to the PC, it mixes with the S-59 and then immediately enters the platelet collection container. Thus, an additional sterile docking procedure is circumvented with this embodiment.

Paragraph beginning on page 234, line 12:

Except for the deviations to be discussed, all of the equipment and procedures in Example 41 are equally applicable here. The process of this example utilizes a three-bag arrangement like that descried above and depicted in [Schematic E]Figure 49. The first bag contains 180 mL of PAS III; the second bag is used to collect autologous plasma in a pre-determined amount; the third bag is the platelet collection bag in which all of the additives are combined.

Paragraph beginning on page 28, line 25:

[FIG. 25A]FIGS. 25A and 25B graphically depict[s] S-59 (C_o = 50 μM) uptake by platelets over time (Figure 25A[top]) and S-59 release by platelets over time (Figure 25B[bottom]).

Paragraph beginning on page 28, line 27:

[FIG. 25B]FIG. 25C is a graph showing the kinetics for adsorption of non-illuminated S-59 (C_o = 50 μM) from 35% plasma/65% PAS III by Amberlite XAD-4™ (0.1 g/3.0 mL) with and without a 24-hour pre-incubation period with S-59 before addition of the adsorbent.

Paragraph beginning on page 29, line 9:

[FIG. 28A]FIGS. 28A, 28B and 28C depict[s] HPLC chromatograms of illuminated 35% plasma/65% PAS III after no treatment (Figure 28A[top]), adsorption with Amberlite XAD-16™ (Figure 28B[middle]), and adsorption with Hemosorba CH-350™ (Figure 28C[bottom]).

Paragraph beginning on page 29, line 12:

[FIG 28B]FIGS. 28D, 28E and 28F depict[s] HPLC chromatograms of 35% plasma/65% PAS III containing non-illuminated S-59 (Figure 28D[top]), illuminated S-59 (Figure 28E[middle]), and illuminated S-59 treated with Amberlite XAD-4™ (Figure 28F[bottom]), and adsorption was contained in a 30 μm nylon mesh enclosure/pouch, and the contact time was three hours.

Paragraph beginning on page 30, line 26:

[FIG. 38]FIGS. 38A and 38B depict[s] a production flow chart of many of the steps used in manufacturing a batch removal device.

Paragraph beginning on page 31, line 4:

[FIG. 41]FIGS. 41A, 41B and 41C depict[s] chromatograms of PC, containing 150 μM S-59 (15.2 mg/300 mL), showing levels of S-59 and free photoproducts before illumination with UVA (Figure 41A[top]), following illumination with UVA (Figure 41B[middle]), and following illumination with UVA and an 8-hour incubation with a RD containing Dowex® XUS-43493 (Figure 41C[bottom]) and housed within a PL 2410 Plastic container (Baxter).